101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03
101. 628-06u – without *Taq* polymerase, IFU-02 Rev. No. 03

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 17N **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*17 SSP

Product number: **101.628-06 – including *Taq* polymerase**
101.628-06u – without *Taq* polymerase
Lot number: **17N**
Expiry date: **2014-August-01**
Number of tests: **6**
Number of wells per test: **12**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-786-01	5	2008-473-05	9	2011-954-09
2	2008-473-02	6	2009-637-06	10	2011-954-10
3	2008-473-03	7	2010-786-07	11	2011-954-11
4	2008-473-04	8	2010-786-08	12	2011-954-12

The specificity of each primer solution of the HLA-C*17 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 and 5 to 12 were available. The specificity of the primers in primer solutions 2, 6, 8 and 12 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 5 and 7 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 9 to 11 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. One additional 3'-primer in primer solution 1 was tested by separately adding one 5'-primer.

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012-February-16

Approved by:

Åsa Claussen

Production Quality Control

CE

101.628-06– including *Taq* polymerase, IFU-01 Rev. No. 03
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Lot No.: 17N **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*17
Product number: 101.628-06
Lot number: 17N

Intended use: HLA-C*17 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2012-February-16

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs